FILED RIDOUT LYON + OTTOSON, LLP 1 CHRISTOPHER P. RIDOUT (State Bar No. 143931) 2014 JAN 27 PM 4: 12 2 Email: c.ridout@rlollp.com CALEB MARKER (State Bar No. 269721) CLERK, U.S. BISTRICT COURT CENTRAL DIST, OF CALIF. LOS ANGELES 3 Email: c.marker@rlollp.com 555 E. Ocean Boulevard, Suite 500 4 Long Beach, CA 90802 (562) 216-7380 (562) 216-7385 Facsimile 5 6 ZIMMERMAN REED, PLLP Bradley C. Buhrow (State Bar No. 283791) 7 Email: brad.buhrow@zimmreed.com 14646 North Kierland Boulevard, Suite 145 8 Scottsdale, AZ 85254 (480) 348-6400 9 (480) 348-6415 Facsimile 10 Attorneys for the Plaintiff 11 UNITED STATES DISTRICT COURT Case No.: SACU 14-115- GA+ (OFM.+) 12 CENTRAL DISTRICT OF CALIFORNIA 13 KYLE DILGER, on behalf of himself and all other similarly situated, 14 COMPLAINT (CLASS ACTION) Plaintiff, 15 For Violations Of: VS. 16 1) Business and Professions Code §§17200 et seq. 23ANDME, INC., a Delaware 17 corporation, 2) Consumer Legal Remedies Act, 18 Civil Code §§1750 et seq. Defendant. 19 (Jury Trial Demanded) 20 Plaintiff Kyle Dilger ("Plaintiff") brings this action, by and through his 21 undersigned counsel, on behalf of himself and all others similarly situated, based on 22 information and belief and the investigation of counsel, except for information based 23 on personal knowledge, and hereby alleges as follows: 24 NATURE OF ACTION 25 This is a consumer protection and false advertising class action. 1. 26 Defendant 23 and Me, Inc. ("Defendant" or "23 and Me") markets, advertises, sells,

COMPLAINT (CLASS ACTION)

distributes, and processes a 23 and Me Saliva Collection Kit and Personal Genome

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Service (collectively, its "Product"). Specifically, Defendant mails a "DNA Spit Kit" to consumers across the United States that is to be returned to Defendant for DNA processing and analysis.

- 2. Through this class action, Plaintiff challenges Defendant's unlawful and unfair business practice of distributing its Product to the public without disclosing that the products are not-FDA approved, misbranded, adulterated, and not known to be accurate.
- 3. Such untrue, deceptive and misleading practices violate California's consumer protection laws and gives rise to claims under the Unfair Competition Law (Cal. Bus. & Prof. Code §§ 17200 et seq., hereinafter referred to as the "UCL"), and the Consumer Legal Remedies Act (Cal. Civ. Code §§ 1750 et seq., hereinafter referred to as the "CLRA"). This Complaint alleges violations of California's Sherman Food, Drug and Cosmetic Act (California Health and Safety Code §§ 110100, et seq. ("Sherman Law") as predicate acts of a violation of Cal. Bus. & Prof. Code § 17200.
- 4. At relevant times during the Class Period, Plaintiff purchased Defendant's Product online at Defendant's website, www.23andme.com.
- 5. At the time of Plaintiff's initial purchase, Defendant did not disclose that the Product (1) was not approved by any governmental regulatory body, including, but not limited to, the Food and Drug Administration ("FDA") and the California Department of Health Services ("DHS"); (2) was misbranded under applicable law; (3) was adulterated under applicable law; and (4) that Defendant did not have analytical or clinical data to support the Products efficacy, making the Product's accuracy questionable due to lack of proper testing (the "Material Omissions").

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- 6. Due to Defendant's deceptive and misleading practices, Plaintiff, at the time of his purchase of Defendant's Product, was unaware of the Material Omissions listed in the preceding paragraph. As a result, Plaintiff mistakenly believed that the Product was accurate and sanctioned by all applicable governmental regulatory bodies.
- 7. As a result of the Defendant's unlawful conduct, Plaintiff, like other Class members, was deprived of the value of the product he purchased. As a result of the Defendant's unlawful conduct, members of the public were likely to be deceived.
- 8. Had Plaintiff known of the Material Omissions, he would not have paid the premium price that he paid for the Product. To wit, Plaintiff paid approximately \$207.00 for Defendant's Product at the time of his purchase in March 2012.
- 9. Plaintiff detrimentally relied on Defendant's deceptive packaging and parted with his money as a result thereof causing financial loss and injury. Based on the foregoing, and as described in greater detail below, this action seeks all remedies permitted by applicable law under the causes of action alleged herein.

#### II. JURISDICTION AND VENUE

- 10. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2), because the proposed class has more than 100 members, the class contains at least one member of diverse citizenship from Defendant, and the amount in controversy exceeds \$5 million.
- 11. The Court has personal jurisdiction over Defendant because it resides in California and is authorized to, and conducts substantial business in, California, generally and this District, specifically. Defendant has marketed, promoted, distributed, and sold the Products throughout California.
- 12. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2), because a substantial part of the events and omissions giving rise to this action occurred in this District as Defendant distributes the Products for sale within this District.

#### III. THE PARTIES

- 13. Plaintiff Kyle Dilger is an adult individual who resides in Orange County, California. He appears individually and on behalf of all those similarly situated as described herein. He asserts all claims in this case on behalf of the Class defined below.
- 14. Defendant 23andMe, Inc. is, and at all times mentioned herein was, a Delaware corporation, with its headquarters, principal place of business and nerve center at 1390 Shorebird Way, Mountain View, California 94043. Defendant's agent for service of process in the State of California is Anne Wojcicki whose registered business address is also 1390 Shorebird Way, Mountain View, California 94043. Defendant distributes the Products to consumers throughout California and throughout the United States.

#### IV. FACTUAL ALLEGATIONS

### A. <u>Defendant's Product</u>

15. Throughout the Class Period, Defendant has marketed, advertised, sold, distributed, and processed its Product – the 23andMe Saliva Collection Kit and Personal Genome Service. Defendant describes its Product as follows:

The 23andMe Personal Genome Service is a comprehensive genetic scan of a subset of the SNPs (single nucleotide polymorphisms) in your genome which correspond to the SNP data being studied by the research community. Individuals provide saliva samples which are analyzed by our CLIA-certified laboratory, and the results are returned to your online account in approximately 6-8 weeks. 23andMe provides both health and ancestry information in a single service for a single price. In addition to the features below, you also have the ability to browse and download your raw genotyped data.

"FAQ: About the 23andMe Personal Genome Service" available online at <a href="https://customercare.23andme.com/entries/22591668-About-the-23andMe-Personal-Genome-Service">https://customercare.23andme.com/entries/22591668-About-the-23andMe-Personal-Genome-Service</a> (last accessed on December 4, 2013).

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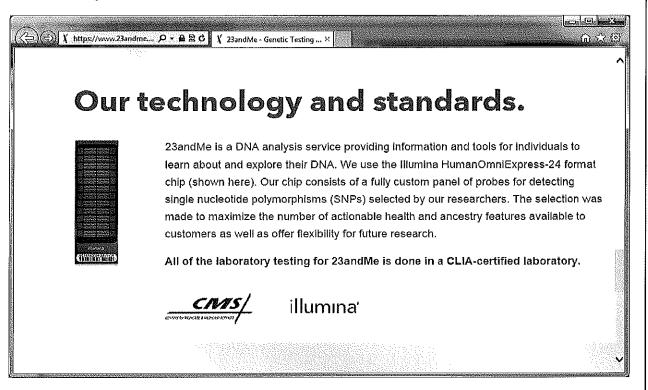
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Upon information and belief, Defendant's Product is sold exclusively 16. on its www.23andme.com website:



- Currently, the Product is sold at a price of \$99.00, but was previously sold at significantly higher prices.
- Defendant's website states that "[g]etting started is simple" and 18. outlines the process: (1) order the DNA spit kit; (2) register the DNA spit kit's bar code online; and (3) return the DNA spit kit to Defendant. "How It Works" available online at <a href="https://www.23andme.com/howitworks">https://www.23andme.com/howitworks</a> (last accessed on December 4, 2013).
- Defendant states that based on a consumer's DNA, it will "provide 19. specific health recommendations" such as whether is a person is at risk of celiac disease (gluten sensitivity), whether you are a carrier for certain mutations that are passed on to children, or at risk for certain drug reactions. *Id.*

20. Under the heading "Our technology and standards", Defendant states the following:



- Id. Notably, Defendant displays the logo of the Centers for Medicare and Medicaid Services in the technology and standards section on its website.
- 21. The Centers for Medicare & Medicaid Services ("CMS"), is a federal agency within the United States Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid. In addition, CMS has other responsibilities, including the administering clinical laboratory quality standards.
- 22. Defendant states the following with regards to the quality of the Product:

How well does the technology work?

The vast majority of the variants on our chip, especially those associated with our Health and specific Ancestry features, have a 98% or greater call rate, meaning that the chip can provide accurate data for more than 98% of those variants in any particular person. Variants for which a confident determination cannot be made are reported as "no calls." A small portion of variants, including those on the sex chromosomes (X and Y) and the

mitochondrial DNA, are difficult to analyze because of biological issues (e.g. pseudogenes, DNA structure, and highly variable regions). These variants will typically have a lower call rate.

While we do not include genetic markers with low call rates in our Health reports, they are still valuable in our ongoing research efforts and so you may see information for some of them in your raw data.

"FAQ: About the 23andMe Personal Genome Service" available online at <a href="https://customercare.23andme.com/entries/22591668-About-the-23andMe-Personal-Genome-Service">https://customercare.23andme.com/entries/22591668-About-the-23andMe-Personal-Genome-Service</a> (last accessed on December 4, 2013).

- 23. On information and belief, the actual DNA Spit Kit packaging is standard packaging that Defendant has distributed and continues to distribute for sale to the public throughout the State of California and the United States during the Class Period. Plaintiff received the standard DNA Spit Kit after placing his order in March 2012.
  - B. <u>Defendant's Product is a Medical Device Requiring Premarket</u>

    <u>Approval</u>
- 24. Under both the FDCA and the Sherman Law, Defendant's Product is a "device" because it is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body. *See* 21 U.S.C. §321(h) and California Health and Safety Code § 109920.
- 25. Additionally, upon information and belief, Defendant's Product has been categorized by the FDA a Class III medical device.<sup>1</sup>
- 26. As such, Defendant's Product is subject to premarket approval by FDA before the Product can be marketed in the U.S.

<sup>&</sup>lt;sup>1</sup> See 21 U.S.C. §360c(a)(1)(C); see also FDA Warning Letter dated November 22, 2013, available online at <a href="http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm">http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm</a> (last accessed December 4, 2013) ("Most of the intended uses for PGS listed on your website...are medical device uses under section 201(h) of the FD&C Act. Most of these uses have not been classified and thus require premarket approval...").

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- The premarket approval ("PMA") is the FDA process of scientific and 27. regulatory review to evaluate the safety and effectiveness of Class III medical devices, such as Defendant's Product.
- Due to the level of risk associated with Class III devices, the FDA 28. has determined that general and special controls alone are insufficient to assure the safety and effectiveness of Class III devices.
- Therefore, new Class III devices must clear FDA premarket review by either PMA<sup>2</sup> or through the "510(k) process."<sup>3</sup>
- PMA is the most stringent type of device marketing application 30. required by the FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by the FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device.
- The regulation governing premarket approval is located in Title 21 31. Code of Federal Regulations (CFR) Part 814, Premarket Approval.
- 32. A Class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FDCA and cannot be marketed.
- In addition to the PMA process, medical devices can receive FDA 33. clearance through the premarket notification, or "510(k)" process.
- Pursuant to the 510(k) process, FDA approval to market a device can 34. be secured by submitting a premarket notification application which establishes that the device is "substantially equivalent" to a Class I or II device already on the market or a Class III device on the market prior to May 28, 1976.<sup>4</sup>

<sup>&</sup>lt;sup>2</sup> 21 U.S.C. §§ 360c(a)(1)(C), 306e. <sup>3</sup> 21 U.S.C. § 360c(f)(1); 360c(b)(1).

See 21 U.S.C. § 360(i)(1)(A); 21 C.F.R. §§ 807.81, 807.87.

Id.

35. Upon information and belief, Defendant submitted its first 510(k) applications for basic FDA approval on July 2, 2012 and September 4, 2012, but has yet to receive any clearance, approval, or certification from the FDA.

36. On November 22, 2013, the Director of the FDA's Public Health Service issued a Warning Letter to Defendant, which stated, in relevant parts, as follows:

"The [FDA] is sending you this letter because you are marketing the [Product] without marketing clearance or approval in violation of the [FDCA]

. . .

Most of the intended uses for [the Product] listed on your website... are medical device uses under section 201(h) of the [FDCA]. Most of these uses have not been classified and thus require premarket approval or de novo classification, as FDA has explained to you on numerous occasions.

FDA Warning Letter dated November 22, 2013, available online at <a href="http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm37629">http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm37629</a> 6.htm> (last accessed December 4, 2013).

37. The Warning Letter further noted that:

Some of the uses for which PGS is intended are particularly concerning, such as assessments for BRCA-related genetic risk and drug responses (e.g., warfarin sensitivity, clopidogrel response, and 5-fluorouracil toxicity) because of the potential health consequences that could result from false positive or false negative assessments for high-risk indications such as these. For instance, if the BRCA-related risk assessment for breast or ovarian cancer reports a false positive, it could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions, while a false negative could result in a failure to recognize an actual risk that may exist.

38. In addition, the Warning Letter noted that after years of exchanges, the FDA still has no "assurance that [Defendant] has analytically or clinically validated the [Product] for its intended uses, which have expanded from the uses that the firm identified in its submissions." *Id*.

- 39. Rather, as of January 9, 2013, Defendant was "completing the additional analytical and clinical validations for the tests that have been submitted' and [was] 'planning extensive labeling studies that will take several months to complete." *Id*.
- 40. Upon information and belief, to date, Defendant has not satisfied any of the Premarket approval requirements for its Product, as Defendant's 510(k) applications are currently considered withdrawn and Defendant has failed to provide adequate information to support a determination that the Product is substantially equivalent to a legally marketed predicate device for any of the uses for which the Product is currently marketed.
- 41. In all, Defendant has been marketing, selling, and distributing the Product to Plaintiff and Class members for a number of years without the required Premarket approval.
- 42. Defendant omits the following from its website, 23andMe.com, and the packaging of its DNA spit kit:
  - a. that Defendant's Product is a medical device, which is not approved by any governmental regulatory body, including, but not limited to, the CMS, the FDA, and DHS;
  - b. that Defendant's product is misbranded under applicable law, including, but not limited to, 21 U.S.C. § 352(o), and California Health and Safety Code §§ 111330;
  - c. that Defendant's product is adulterated under applicable law, including, but not limited to, 21 U.S.C. § 351(f)(1)(B);
  - d. that Defendant's Product is not known to be accurate;
  - e. that Defendant's Product may report inaccurate results;
  - f. that Defendant's Product may report false positives or false negatives; and

- g. that Defendant's Product was subject to an on-going governmental investigation.
- 43. On information and belief, the 23andMe website described in the paragraphs has been materially consistent throughout the Class Period.
- 44. Plaintiff reviewed the www.23andMe.com website before placing his purchase in March 2012.
- 45. As a result, Plaintiff and other Class members were unaware of the material omissions identified in Paragraph 5 above.
  - C. <u>Plaintiff's Claims Are Predicated On Violations of California's</u>
    Sherman Food, Drug, and Cosmetic Law
- 46. The FDCA includes an explicitly preemption provision in the form of section 360k(a), which provides:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement- 1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and 2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

- 47. Although section 360k speaks in terms of what states may *not* do, by negative implication, section 360k also expresses what state *may* do, i.e., states *may* establish their own requirements pertaining to a requirement for a medical device so long as the state's requirements are identical to the requirements of the FDCA.
- 48. As provided below, Plaintiff's claims are predicated on, among other things, Defendant's violations of California's Sherman Food, Drug, and Cosmetic Law.
- 49. The sections of the Sherman Law Plaintiff claims Defendant violated as predicates violations of the UCL parallel the federal requirements under the FDCA.

- 50. Plaintiff is not seeking to enforce, or to restrain violations of the FDCA. Rather, Plaintiff's claims are predicated on California state laws establishing independent state requirements identical to the requirements imposed by the FDCA, something Congress explicitly approved in section 360k of the FDCA.
  - 51. As such, Plaintiff's claims are not preempted by federal law.

#### V. INJURY AND DAMAGE

- 52. By selling the Product exclusively through its own website, Defendant ensured that Plaintiff and all Class members would be subject to the same material representations and omissions.
- 53. Plaintiff and the members of the Class suffered actual and direct injury, incurred damage and financial loss as a result of Defendant's conduct complained of herein. Among other things, Plaintiff and the Class paid a premium price for the 23andMe Product purchased the Product unaware of the material omissions identified in Paragraph 5.
- 54. Had Plaintiff known of the material omissions identified in Paragraph 5, he would not have paid the premium price that he paid. Rather, he would have paid less money for the Product and/or purchased a substitute Product. By omitting said information, Defendant injured Plaintiff and the members of the Class, caused them damage and caused them to incur out-of-pocket financial loss.

#### VI. CLASS ACTION ALLEGATIONS

55. Plaintiff seeks relief in his individual capacity and seeks to represent a class consisting of all others who are similarly situated. Pursuant to Fed. R. Civ. P. 23(a) and (b)(2) and/or (b)(3), Plaintiff seeks certification of a class initially defined as follows:

All persons residing in the United States who purchased Defendant's 23andMe Saliva Collection Kit and Personal Genome Service from the www.23andMe.com website at any time during the Class Period (hereinafter, the "Class").

The "Class Period" dates back four years (or the length of the longest applicable statute of limitations for any claim asserted) from the date this action was commenced and continues through the present and the date of judgment. Specifically excluded from the Class are: (a) any officers, directors or employees of the Defendant; (b) any judge assigned to hear this case (or spouse or immediate family member of any assigned judge); (c) any employee of the Court; (d) any juror selected to hear this case; and (e) any attorneys' of record and their employees.

- 56. **Numerosity of the Class.** Members of the Class are so numerous that their individual joinder herein is impracticable. The precise number of members of the Class and their addresses are presently unknown to Plaintiff, but is believed to exceed 1,000 people.
- 57. **Ascertainable Class.** The proposed Class is ascertainable from objective criteria.
- 58. Common Questions of Fact and Law Exist and Predominate over Individual Issues. There is a well-defined community of interest in the questions of law and fact involved affecting the parties to be represented. These common questions of law and fact exist as to all members of the Class and predominate over the questions affecting only individual members of the Class. These common legal and factual questions include without limitation:
  - a) Whether Defendant's failure to inform Plaintiff and Class members that the Product is adulterated under applicable law constitutes a material omission likely to deceive a consumer;
  - b) Whether Defendant's failure to inform Plaintiff and Class members that the Product is misbranded under applicable law constitutes a material omission likely to deceive a consumer;
  - c) Whether Defendant's failure to inform Plaintiff and Class members that the Product is not known to be accurate and/or may

- report false positives or false negatives constitutes a material omission likely to deceive a consumer;
- d) Whether Defendant violated California Civil Code §§ 1750, et seq. by omitting that the Product did not have the previously specified sponsorship, approval, characteristics, uses, or benefits.
- e) Whether Defendant violated California Business and Professions Code §§ 17200, et seq.; and
- f) Whether Plaintiff and Class members sustained injury and damages resulting from Defendant's conduct and, if so, the proper measure of damages, restitution, equitable, or other relief, and the amount and nature of such relief.
- 59. **Typicality.** Plaintiff's claims are typical of the claims of members of the Class. Typical of other class members, Plaintiff purchased Defendant's Product using Defendant's www.23andMe.com website. Plaintiff and the Class members each sustained damages arising from Defendant's common course of wrongful conduct, as alleged more fully herein. Plaintiff's claims are founded on the same legal theories as those of the Class. The effort Plaintiff undertakes to pursue his own claim will significantly benefit the Class members because of the identical nature of the issues across the Class.
- 60. Adequacy of Representation. Plaintiff will fairly and adequately represent and protect the interest of the members of the Class. Plaintiff shares a common interest with the Plaintiff Class members, with respect to the conduct of the Defendant herein and redress of injury. Plaintiff has suffered an injury-in-fact as a result of the conduct of the Defendant, as alleged herein. Plaintiff has retained counsel who are competent and experienced in the prosecution of complex consumer fraud, mass tort and class actions. Plaintiff and his counsel intend to prosecute this action vigorously and faithfully for the benefit of the Class

members. Plaintiff has no interests contrary to the class members, and will fairly and adequately protect the interests of the Class.

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- 61. Community of Interest. The proposed Class has a well defined community of interest in the questions of fact and law to be litigated. The common questions of law and fact are predominant with respect to the liability issues, relief issues and anticipated affirmative defenses. The named Plaintiff has claims typical of the Class members. Without limitation, as a result of Defendant's conduct alleged herein, Plaintiff was: (a) injured; (b) deprived of the value of the products that he bargained for; and (c) sustained pecuniary loss in an ascertainable amount to be proven at the time of trial.
- Superiority of Class Adjudication. The certification of a class in this 62. action is superior to the litigation of a multitude of cases by members of the putative class. Class adjudication will conserve judicial resources and will avoid the possibility of inconsistent rulings. Moreover, there are Class members who are unlikely to join or bring an action due to, among other reasons, their reluctance to spend large sums of time and money to recover what may be a relatively modest individual recovery. Equity dictates that all persons who stand to benefit from the relief sought herein should be subject to the lawsuit and hence subject to an order spreading the costs of the litigation among the class members in relationship to the benefits received. The damages, restitution and other potential recovery for each individual member of the Class are modest given the low-purchase price of the consumer products at issue, relative to the substantial burden and expense of individual prosecution of these claims. Given the amount of the individual Class members' claims, few, if any, Class members could or would afford to seek legal redress individually for the wrongs complained of herein. Even if the members of the Class themselves could afford individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory judgments. Individualized

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litigation increases the delay and expense to all parties and the court system presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court.

- 63. In the alternative, the above-referenced Class may be certified because:
  - a) The prosecution of separate actions by the individual members of the Class would create a risk of inconsistent or varying adjudication with respect to individual Class members' claims which would establish incompatible standards of conduct for Defendant;
  - b) The prosecution of separate actions by individual members of the Class would create a risk of adjudications which would as a practical matter be dispositive of the interests of other members of the Class who are not parties to the adjudications, or which would substantially impair or impede the ability of other Class members to protect their interests; and,
  - c) Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final and injunctive relief with respect to the Class.

#### VII. CLAIMS FOR RELIEF

#### **COUNT I - UNFAIR AND DECEPTIVE PRACTICES**

## (Violation of the California Consumers Legal Remedies Act)

- 64. Plaintiff fully incorporates by reference herein all of the above paragraphs, as though fully set forth herein.
- 65. This cause of action is brought pursuant to the California Consumers Legal Remedies Act, Cal. Civ. Code §§1750, et seq. (the "CLRA").

- 66. Defendant's actions, representations, and conduct have and continue to be subject to the CLRA because they extend to transactions that are intended to result, or that have resulted, in the sale of goods to consumers.
- 67. Plaintiff and the proposed Class members are "consumers" within the meaning of Cal. Civ. Code §1761(d).
  - 68. Defendants are "persons" as defined by Cal. Civ. Code §1761(c).
- 69. Defendants sold to Plaintiff and other Class members its Product which is a good within the meaning of California Civil Code §1761(a). The goods at issue were purchased by Plaintiff and the Class for personal and/or household use.
- 70. By engaging in the deceptive acts and practices set forth in this complaint, Defendant violated, and continues to violate Sections 1770(a)(5) and(9) of the CLRA, which expressly prohibit:
  - (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which he or she does not have; and
  - (9) Advertising goods or services with intent not to sell them as advertised.
- 71. Specifically, Defendant violated, and continues to violate, Section 1770(a)(5) of the CLRA by omitting Defendant's failure to obtain FDA approval of the device at the time of purchase and the other material omissions identified in Paragraph 5.
- 72. Defendant also violated, and continues to violate, Section 1770(a)(5) of the CLRA by representing that its Product has sponsorship, approval or is otherwise endorsed by the CMS, FDA and/or DHS when, in fact, it does not.
- 73. In addition, Defendant violated, and continues to violate Section 1770(a)(9) of the CLRA by advertising the Product on its website and product packaging without the intent to sell it as advertised.

- 74. Plaintiff justifiably relied on Defendant's conduct, causing him injury. Plaintiff paid a premium price for the Product that he purchased without any knowledge of the material omissions identified in Paragraph 5. Plaintiff was injured in fact and lost money as a result of Defendant's conduct of improperly advertising the Product through misleading packaging.
- 75. Defendant has engaged and continues to engage in the above-described conduct that is prohibited by the CLRA. Plaintiff and the Class members have suffered, and continue to suffer, harm and actual and direct injury as a proximate result of the violations of law and wrongful conduct of Defendant as alleged herein.
- 76. Pursuant to CLRA §1782, Plaintiff provided written notice to Defendant of the asserted violations of CLRA §1770 and demanded that Defendants rectify the conduct described above. Plaintiff mailed said notice to Defendant via certified mail, return receipt requested, on January 23, 2014. This notice and demand notified Defendant of its above mentioned violations of the CLRA that harmed Plaintiff and the members of the Class of consumers that Plaintiff represents, and demanded that Defendant cease engaging in and remedy the violations.
- 77. As of today, Defendant continues to violate the CLRA as specified above.

#### **COUNT II - UNFAIR AND DECEPTIVE PRACTICES**

## Violation of California Business & Professions Code §§17200, et seq.

- 78. Plaintiff fully incorporates by reference all of the above-stated paragraphs, as though fully set forth herein.
- 79. The Unfair Competition Law, Bus. & Prof. Code §§17200, et seq. prohibits unfair competition, defined as "any unlawful, unfair or fraudulent business act or practice." Under the statute there are three varieties of unfair competition: practices that are unlawful, unfair or fraudulent, each of which is

separately and independently actionable. Here, Plaintiff's UCL claims are only predicated solely on Defendant's "unlawful" conduct. Plaintiff's UCL claim is not based on the fraudulent or unfair prong of the UCL.

- 80. Defendant has engaged in unlawful business acts and practices in violation of Section 17200 of the Business and Professions Code, and which included, but are not limited to:
  - a. Defendant made, or caused to be made, untrue and misleading material omissions regarding its Product as more fully described above, in violation of Civil Code 1770(a)(5); and
  - b. Defendant made, or caused to be made, untrue and misleading material omissions regarding its Product as more fully described above, in violation of Civil Code 1770(a)(9).
- 81. Defendant has further engaged in unlawful business acts and practices in violation of Section 17200 of the Business and Professions Code by violating sections of California's Sherman Act, California Health & Safety Code §§110100 *et seq.*, which protects consumers against the misbranding, adulteration, and mislabeling of, among other things, drugs and devices.
- 82. Specifically, Defendant's actions described above violated sections of the Sherman Act, which include, but are not limited to:
  - a. Defendant made, or caused to be made, untrue and misleading representations regarding its Product in its marketing and advertising in violation of California Health & Safety Code §§110390, 110395, and 110398;
  - b. Defendant made, or caused to be made, untrue and misleading representations regarding its Product in its marketing and labeling in violation of California Health & Safety Code §§111330, 111440, and 111445;

- c. Defendant marketed, sold, advertised, or otherwise placed into the stream of commerce, a new device, as that term is defined by both the FDCA and the Sherman Law, which required premarket approval before being marketed or sold in the US, in violation of California Health & Safety Code §111550.
- 83. The conduct of Defendant as set forth above demonstrates the necessity for granting injunctive relief restraining such and similar acts of unfair competition pursuant to California Business and Professions Code Section 17203 and 17535. Unless enjoined and restrained by Order of this Court, Defendant will retain the ability to, and may engage in, said acts of unfair competition and misleading packaging.
- 84. As a result of the above-stated conduct, on behalf of the Class, Plaintiff seeks injunctive relief, restitution, disgorgement of ill-gotten gains, attorneys' fees, and all other remedies and relief that may be permitted by law and equity.

#### VIII. PRAYER FOR RELIEF

WHEREFORE, on behalf of himself and the Class, Plaintiff prays for judgment as follows:

- A. For an order certifying that the action may be maintained as a class action and appointing Plaintiff and his undersigned counsel to represent the Class in this litigation;
- B. For an order declaring that the acts and practices of Defendants constitute violations of California Business & Professions Code §17200, et seq. and California Civil Code §1750, et seq.
- C. For restitution of monies wrongfully obtained and/or disgorgement of ill-gotten revenues and/or profits;

D. For a permanent injunction enjoining Defendant from continuing to 1 harm Plaintiff and the members of the Class, and the public, and violating California 2 law in the manners described above; 3 E. For actual damages; 4 For reasonable attorneys' fees and the costs of the suit; and F. 5 For all such other relief as this Court may deem just and proper and G. 6 may be available at law or equity. 7 IX. DEMAND FOR TRIAL BY JURY 8 Plaintiff seeks a trial by jury for all appropriate issues on each and every cause 9 of action in this Complaint that allows for it. 10 11 Respectfully submitted, 12 RIDOUTLYON + OTTOSON LLP 13 14 Dated: January 22, 2014 By: Christopher P. Ridout (State Bar No. 143931) Caleb Marker (State Bar No. 269721) 555 E. Ocean Boulevard, Suite 500 15 16 Long Beach, CA 90802 (562) 216-7380 17 (562) 216-7385 Facsimile 18 Bradley C. Buhrow (State Bar No. 283791) ZIMMERMAN REED, PLLP 19 14646 North Kierland Boulevard, Suite 145 Scottsdale, AZ 85254 20 (480) 348-6400 (480) 348-6415 21 brad.buhrow@zimmreed.com 22 Attorneys for Plaintiff 23 24 25 26 27 28

# UNITED STATES DISTRICT COURT CENTRAL DISTRICT OF CALIFORNIA

#### NOTICE OF ASSIGNMENT TO UNITED STATES JUDGES

This case has been assigned to Di	strict Judge	Gary A. Fee	ess a	and the assigned
Magistrate Judge is Douglas F. N	AcCormick .			
The case number on all	documents filed with th	e Court shoul	d read as follows	s:
	SACV14-115-GAF(I	OFMx)		
Pursuant to General Order 05-07 California, the Magistrate Judge has beer				strict of
All discovery related motions sho	ould be noticed on the ca	alendar of the	Magistrate Judg	e.
		Clerk, U. S. Di	strict Court	
January 27, 2014	Ī	By Rhonda M	acroball	
Date	1	Deputy Cle		
	NOTICE TO COUN	ISEL		
A copy of this notice must be served with filed, a copy of this notice must be served		laint on all dej	fendants (if a ren	noval action is
Subsequent documents must be filed at	t the following location	:		
Western Division 312 N. Spring Street, G-8 Los Angeles, CA 90012	Southern Division 411 West Fourth St., Ste Santa Ana, CA 92701	1053	Eastern Division 3470 Twelfth Str Riverside, CA 92	eet, Room 134
Failure to file at the proper location wi	ll result in your docum	ents being re	turned to you.	

## UNITED STATES DISTRICT COURT

for the

Central District of California

KYLE DILGER, on behalf of himself and all other similarly situated,	
Plaintiff(s) v. 23ANDME, INC., a Delaware corporation,	Civil Action No.  SACV 14-115- GAF (OFMX)
Defendant(s)	

#### SUMMONS IN A CIVIL ACTION

To: (Defendant's name and address) 23andMe, Inc.
1390 Shorebird Way
Mountain View, California 94043

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney,

whose name and address are:

Christopher P. Ridout, Esq

Caleb Marker, Esq.

RIDOUT LYON + OTTOSON, LLP 555 E. Ocean Blvd., Ste. 500 Long Beach, CA 90802 (562) 216-7380

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

Date: 1-27-14

CLERK OF COURT

Signature of Clerk or Deput

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

#### PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (1))

	This summons for (nar	ne of individual and title, if any)		
was re	ceived by me on (date)	·		
	☐ I personally served	the summons on the individual	at (place)	
			on (date)	; or
	☐ I left the summons	at the individual's residence or	usual place of abode with (name)	
		, a perso	on of suitable age and discretion who res	sides there,
	on (date)	, and mailed a copy to	the individual's last known address; or	
	☐ I served the summo	ons on (name of individual)		, who is
	designated by law to	accept service of process on beh	alf of (name of organization)	
			on (date)	; or
	☐ I returned the summ	nons unexecuted because		; or
	Other (specify):			
	My fees are \$	for travel and \$	for services, for a total of \$	0.00
	I declare under penalty	y of perjury that this information	is true.	
Date:			G	
			Server's signature	
			Printed name and title	
			Server's address	

Additional information regarding attempted service, etc:

## UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA CIVIL COVER SHEET

		0,1,2,00			
	ox if you are representing yourself alf of himself and all other similar		DEFENDANTS 23ANDME, INC., a Del	aware corporation,	
(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.) Christopher P. Ridout, Esq. (SBN 143931), Caleb Marker, Esq. (SBN 269721) Ridout Lyon + Ottoson, LLP. Add: 555 E. Ocean Bivd., Ste., 500, Long Beach, CA 90802, Tel: (562) 216-7380; Fax: (562) 216-7385			Attorneys (If Known)		
II. BASIS OF JURISDICTIO	N (Place an X in one box only.)		NSHIP OF PRINCIPAL PAR TX in one box for plaintiff and	-	es Only
☐ I U.S. Government Plaintiff	☐ 3 Federal Question (U.S. Government Not a Party	·	PJ	F DEF	
☐ 2 U.S. Government Defendan	of Parties in Item III)	·		of Business in A	
		Citizen or Sul	ject of a Foreign Country 🔲	3 □ 3 Foreign Nation	□6 □6
IV. ORIGIN (Place an X in one box only.)  1 Original Proceeding State Court Appellate Court Reopened Reopened State Court Proceeding State Court Proceeding State Court Appellate Court Proceeding State Court Appellate Court Reopened State Court Proceeding State Court Appellate Court Reopened State Court Proceeding State Court Appellate Court Reopened State Court Proceeding State Court State Court Proceeding State Court State Court State Court Proceeding State Court State Court State Court Proceeding State Court State					
CLASS ACTION under F.R.C	C.P. 23; M Yes □ No		MONEY DEMANDED IN	COMPLAINT: \$ 5,000,00	00
VI. CAUSE OF ACTION (Cit	te the U.S. Civil Statute under whi	ch you are filing and u	rite a brief statement of cause	Do not cite invisdictional s	tatutas unlass divarsity )
28 USC 1332 (d); Consum		cir you are minig and w	The a offer statement of cause.	Do not one junisalenonal s	tatutes unless utversity.)
VII. NATURE OF SUIT (Plac					
THE THE OWN OF BUILDING	te an X in one box only.)	<del></del>			1
OTHER STATUTES  400 State Reapportionment 410 Antitrust  430 Banks and Banking  450 Commerce/ICC Rates/etc.  460 Deportation  470 Racketeer Influenced and Corrupt Organizations  480 Consumer Credit  490 Cable/Sat TV  810 Selective Service  850 Securities/Commodities/ Exchange  875 Customer Challenge 12 USC 3410  890 Other Statutory Actions 891 Agricultural Act  892 Economic Stabilization Act  893 Environmental Matters 894 Energy Allocation Act  895 Freedom of Info. Act  900 Appeal of Fee Determination Under Equal Access to Justice  950 Constitutionality of State Statutes	Overpayment of Veteran's Benefits  160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise REAL PROPERTY 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability 290 All Other Real Property	TORTS PERSONAL INJUI  310 Airplane Prod Liability  320 Assault, Libel Slander  330 Fed, Employe Liability  340 Marine  345 Marine Product Liability  350 Motor Vehicle Product Liabil  360 Other Personal Injury  362 Personal Injury  Assault, Libel Product Liabil  363 Asbestos Personal Injury Product Liabil  364 Asbestos Personal Injury Product Liability  MMMIGRATION  462 Naturalization Application  463 Habeas Corpus Alien Detainec  465 Other Immigra Actions	PROPERTY  ## 370 Other Fraud    370 Other Fraud   371 Truth in Lending   380 Other Personal   Property Damag   Product Liability   BANKRURTOV   422 Appeal 28 USC   158   423 Withdrawal 28   USC 157   EIVIERIGHTS   441 Voting   442 Employment   443 Housing/Acco-   mmodations   444 Welfare   445 American with   Disabilities -   Employment   446 American with   Disabilities -   Other Civil   Rights	☐ 530 General e ☐ 535 Death Penalty e ☐ 540 Mandamus/ Other	☐ 791 Empl. Ret. Inc. Security Act PROPERTY RIGHTS ☐ 820 Copyrights ☐ 830 Patent ☐ 840 Trademark SOCIAT SECURITY
mar					
FOR OFFICE USE ONLY: Case Number:					
AFTER CO	OMPLETING THE FRONT SH	DE OF FORM CV-71	COMPLETE THE INFORT	MATION REQUESTED E	RELOW

SACV LH-115

## UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Ha If yes, list case number(s):	s this action been p	reviously filed in this court a	nd dismissed, remanded or closed? ☑ No ☐ Yes	
VIII(b). RELATED CASES: Hav If yes, list case number(s):	e any cases been pro	eviously filed in this court the	at are related to the present case? 🗹 No 🖂 Yes	
□ C.	Arise from the sam Call for determinat For other reasons w	e or closely related transactic ion of the same or substantial would entail substantial duplic	ons, happenings, or events; or Ily related or similar questions of law and fact; or cation of labor if heard by different judges; or t, <u>and</u> one of the factors identified above in a, b or c also is present.	
IX. VENUE: (When completing the	following informat	tion, use an additional sheet i	f necessary.)	
<ul><li>(a) List the County in this District;</li><li>☐ Check here if the government, i</li></ul>	California County of ts agencies or emple	outside of this District; State to	if other than California; or Foreign Country, in which <b>EACH</b> named plaintiff resides. this box is checked, go to item (b).	
County in this District;*			California County outside of this District; State, if other than California; or Foreign Country	
Orange County				
(b) List the County in this District;  ☐ Check here if the government, in	California County of a agencies or emplo	outside of this District; State in our side of this District; State in our side of the outside outside of the outside outsid	if other than California; or Foreign Country, in which <b>EACH</b> named defendant resides. If this box is checked, go to item (c).	
County in this District:*			California County outside of this District; State, if other than California; or Foreign Country	
orange county			Delaware corporation, with its headquarters, principal place of business and nerve center at 1390 Shorebird Way, Mountain View, California 94043	
(c) List the County in this District, Note: In land condemnation ca	California County o	outside of this District; State i	if other than California; or Foreign Country, in which <b>EACH</b> claim arose.	
County in this District:*			California County outside of this District; State, if other than California; or Foreign Country	
orange county				
* Los Angeles, Orange, San Bernar Note: In land condemnation cases, us	dino, Riverside, V	entura, Santa Barbara, or S	San Luis Obispo Counties	
X. SIGNATURE OF ATTORNEY (OR PRO PER): Date January 22, 2014				
or other papers as required by lav	v. This form, approx	ed by the Judicial Conference	mation contained herein neither replace nor supplement the filing and service of pleadings e of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed ing the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)	
Key to Statistical codes relating to So	cial Security Cases;	;		
Nature of Suit Code	Abbreviation	Substantive Statement of	Cause of Action	
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))		
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)		
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))		
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))		
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.		
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))		

CV-71 (05/08)